HENNINGSEN FOODS INC.

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane , Room 1061
Rockville, MD. 20852

Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203 and 2000N-0504

Dear Sir or Madam:

The purpose of this letter is to comment on the Food and Drug Administration's proposed rule on Salmonella Enteritidis in shell eggs. Our company, Henningsen Foods Inc., employs approximately 130 people at our processing and drying operation in David City, Nebraska. We maintain 1.6 million hens in 18 houses at 10 different contract farms within a 50 mile radius of our breaking plant. All of our shell eggs are dedicated to breaking and pasteurizing.

Since 1972 we have pasteurized egg products under regulations first established by the Agricultural Marketing Service and later transferred to the authority of the Food Safety and Inspection Service. During this time period we have never heard of any salmonellosis outbreak that was traced to an egg product. All egg products are produced under strict controls of sanitation, cooling and pasteurization. Each lot of product is tested salmonella negative using officially approved methods as a final verification step. The documented control of microbiological hazards by the egg products industry is matched by very few other food processors. It comes as no surprise to those of us in the industry that egg products have an exemplary food safety record, mathematical models notwithstanding.

As a potential participant in the plan for the elimination of SE in table eggs, Henningsen Foods has a strong interest in how this FDA rule might affect our FSIS-inspected operations. Since the refrigeration requirement of the rule is the only portion that could directly affect our operations we will confine our comments to that area.

1. The requirement that shell eggs be stored at 45F if held at the farm for longer than 36 hours is not practical. Over weekends and holidays 36 hours is just not enough time. The temperature of 45F is also too low for shell eggs dedicated to breaking. Currently our shell eggs at the farms are stored at around 55F and a decrease to 45F will likely increase the number of thermal checks coming out of the washers resulting in lower yields and possibly more salmonella in the raw products. An additional consequence will be a drop in our egg white yields, as lower shell egg temperatures tend to make more egg white stay with the shells after breaking.

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2. In the case of non-restricted shell eggs i.e. nest run eggs, we think 60F for up to 2 weeks between lay and break is reasonable. Based on a survey of egg products plants conducted for FSIS by RTI International and published on June 30, 2004 these parameters are in-line with current industry practice.

3. The wording and structure of the proposed rule seems to suggest that the 45F after 36 hours requirement was designed by FDA first and foremost with table eggs in mind and second with the idea that SE positive table eggs may be diverted to in-shell pasteurization. However, the overall process of shell egg breaking, separation, cooling, liquid storage and pasteurizing according to FSIS regulations is a world apart from in-shell pasteurization, especially in terms of the increased ability of the pasteurizing step to destroy salmonella. It therefore follows that the refrigeration requirement for shell eggs dedicated to breaking and pasteurization should not necessarily be the same as those for table eggs.

4. We wonder whether FDA has collaborated well enough with FSIS on the subject of refrigeration of shell eggs dedicated to breaking and pasteurization. As you know FSIS is in the process of setting pasteurization performance standards for egg products. Will your refrigeration requirements affect FSIS thinking in the setting of those standards? Does it make sense to have on-farm refrigeration under FDA control and the rest of egg product operations under FSIS jurisdicton?

Henningsen Foods is willing to be part of the solution to the problem of SE in table eggs. However we do not want our operation and others like it to be needlessly and adversely affected by the SE-driven refrigeration requirements found in the proposed rule. We respectfully ask that FDA discuss in depth the subject of refrigeration requirements for shell eggs dedicated to breaking and pasteurizing with the appropriate personnel at FSIS. Perhaps it would be best to separate these requirements in the rule from those for table eggs or even defer the matter entirely to FSIS rulemaking.

For Henningsen Foods Inc.

Jim Gilliam

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DATE: November 30, 2004

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